

CERTIFICATE OF ANALYSIS

Product Name	Ursodeoxycholic Acid	Batch No	PY-UR20190821
Quantity	300KG	Analysis Date	Aug.24,2019
Mfg. Date	Aug.21,2019	Exp. Date	Aug.20,2021
Package	25kg/Drum	Standard	USP42

No.	Item	Specification	Result
1.	Appearance	White or almost white powder	Complies
2.	Melting Point	200°C~205°C	Complies
3.	Identification	IR Identification: The infrared absorption spectrum of sample is completely in conformity with the spectrum of ursodeoxycholic acid CRS.	Complies
4.	Loss on Drying	≤0.5%	0.20%
5	Specific Optical Rotation	+57.0° ~ +62.0°	+59.7°
6.	Related Substance(by TLC)	Chenodeoxycholic acid≤1.5% Any unspecified single Impurities≤0.1% Lithocholic acid: ≤0.05%	Complies Complies Complies
7.	Sulphated Ash	≤0.1%	Complies
8.	Heavy Metals	≤10ppm	<10ppm
9.	Assay	98.5%~101.5%	100.1%
10.	Conclusion	Conform to theUSP42 Standard.	

Analyst: xuli

QC: lixiaochen